Charles E. Lipsey (pro hac vice)
Edna Vassilovski (pro hac vice)
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
1300 I Street, N.W., Suite 700
Washington, D.C. 20005-3315
Telephone: (202) 408-4000
Facsimile: (202) 408-4400

Thomas W. Banks (SBN 195006)
John W. Burns (SBN 190031)
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
700 Hansen Way
Palo Alto, California 94304
Telephone: (650) 849-6600
Facsimile: (650) 849-6666

WRIGHT & L'ESTRANGE
John H. L'Estrange, Jr. (SBN 49594)
Imperial Bank Tower, Suite 1550
701 "B" Street
San Diego, California 92101-8103
Telephone: (619) 231-4844

Attorneys for Defendant VYSIS, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

CASE NO. 99CV 2668H (AJB)

DECLARATION OF DAVID J. LANE, Ph.D. IN SUPPORT OF MOTION OF VYSIS, INC. TO COMPEL GEN-PROBE, INCORPORATED TO PRODUCE RESEARCH AND DEVELOPMENT AND COMMERCIAL SUCCESS DOCUMENTS

Date: December 12, 2000
Time: 11:00 A.M.
Dept.: Courtroom A

I, David J. Lane, Ph.D. declare and state as follows:

1. My name is David J. Lane. I have personal knowledge of the facts set forth in this declaration. Those facts are true.

2. I am presently a Senior Director in Research and Development ("R&D") with Vysis, Inc. ("Vysis") in Downer's Grove, Illinois. I have been with Vysis since 1995. My work with Vysis has been concentrated mainly in the areas of nucleic acid-based diagnostic assays for infectious diseases and nucleic acid-based microarray technology. From 1985 to 1995 I was employed in Framingham, Massachusetts by a succession of business entities that can generally be referred to as Gene-Trak Systems or, more simply, Gene-Trak. The Gene-Trak entities or their successors are now owned by Vysis. My work at Gene-Trak was predominantly in the area of nucleic acid-based diagnostic assays for infectious diseases.

3. I received a B.S. in Biology from the State University of New York at Stony Brook in 1973. I was awarded a Ph.D. in Biophysics, Biochemistry & Genetics from the University of Colorado Health Services Center, Denver, CO in 1983.

4. I am familiar with the technology that is the subject of Vysis's U.S. Patent No. 5,570,338 ("'338 patent") at issue in this case. I understand that the patent generally discloses and claims methods (assays) for amplifying and/or detecting a target polynucleotide in a sample using the steps of target capture and amplification. A polynucleotide is a portion of the nucleic acid (e.g., DNA) of an organism. In nucleic acid-based diagnostics, certain specific polynucleotides can be used to identify target organisms. Target capture refers to separating the target polynucleotide from the other components of a sample, including substances that might interfere with subsequent steps of a diagnostic assay, and other "non-target" polynucleotides. Amplification refers to making many copies of the target polynucleotide (or its complement), by a variety of in vitro molecular techniques that are well known in the literature, so that the target polynucleotide can be detected and/or measured.

5. I was extensively involved in efforts by Gene-Trak in the early 1990's to develop an automated instrument for detecting target polynucleotides in samples using target capture and amplification, as taught and claimed by the '338 patent. My work on this project included oversight of R&D efforts in probe development, sample processing and amplification technology.

6. I became aware from Gen-Probe's public presentations in the late 1980's to mid-1990's that Gen-Probe was developing or attempting to develop manual and automated assays for detecting target polynucleotides in a sample. I understand that Gen-Probe introduced the PACE assay in about 1988, followed by the PACE II assay in about 1991. Both were manual assays that did not include an amplification step. In about 1995, Gen-Probe introduced its manual assay for *Mycobacterium tuberculosis* using an amplification step called Transcription Mediated Amplification (TMA). I became aware in about 1997 that Gen-Probe sought to introduce an instrument, called the TIGRIS, to automate their TMA assays. To my knowledge, the instrument was first depicted publicly (e.g., in 1997 at the national meeting of the American Society for Microbiogy in Miami Beach) as including an automated "sample processing module." However, to the best of my recollection, the components of this sample processing module were not publicly disclosed at the time. None of the Gen-Probe manual assays, PACE, PACE II, or the TMA-based assays sold during this time used target capture.

7. During the fall of 1994, Gene-Trak and Gen-Probe explored the possible complementarity of certain of their respective technologies. Specifically, this included a single joint experiment to combine Gene-Trak's target capture with Gen-Probe's PACE and PACE II assays. Gene-Trak provided Gen-Probe with substantial know-how with respect to target capture during the experiment. The experiment did not lead to further investigation of combining these technologies.

8. In the 1995-96 period, Gen-Probe hired three former Gene-Trak employees Will Weisburg, Jay Shaw, and Tom Shimei. All three worked extensively on Gene-Trak's development of an automated assay using target capture and amplification.

9. In 1998, after Gen-Probe hired the ex-Gene-Trak researchers, I became aware for the first time that Gen-Probe was developing target capture methods and combining them with its TMA amplification method in assays for detecting target polynucleotides. Gen-Probe presented technical posters describing manual assays for detecting polynucleotides in a sample using both target capture and amplification at the national meeting of the American Society for Microbiology in Atlanta Georgia in the spring of 1998. Ex-Gene-Trak researcher Jay Shaw was an author on one of the posters describing such an assay for Chlamydia and Neisseria gonorrhoeae (C-41, attached hereto as

Exhibit A.). The abstract explicitly states, "This assay format will be fully automated on the TIGRIS instrument." Another Gen-Probe poster exhibited at the same meeting (C-132, attached hereto as Exhibit A.) describes an amplified target capture assay for the quantitative determination of HIV-1 RNA in plasma of AIDS patients.

10. At the 1999 national meeting of the American Society for Microbiology in Chicago, I had a discussion with ex-Gene-Trak researcher Tom Shimei, who was working at a Gen-Probe booth displaying Gen-Probe's TIGRIS automated instrument for detecting target polynucleotides. Mr. Shimei explained that the TIGRIS instrument now used both target capture and amplification. Mr. Shimei, along with ex-Gene-Trak researcher Jay Shaw and others, also had a poster at that meeting describing the TIGRIS instrument. (C-127, attached hereto as Exhibit B.) Again, it is clear from the abstract that the TIGRIS employs both target capture and amplification. As stated in the abstract, "Sample processing is accomplished with Target Capture technology. Specific nucleic acid sequences are captured onto magnetic microparticles. Purified nucleic acids are then amplified isothermally by Transcription-Mediated Amplification (TMA)." Jay Shaw and others from Gen-Probe also presented a poster at this meeting describing Gen-Probe's nucleic acid-based assay for Chlamydia trachomatis and Neisseria gonorrhoeae using target capture and amplification. (C-126, attached hereto as Exhibit B.)

11. It is my understanding that Gen-Probe's commercial nucleic acid test ("NAT") kits for screening blood samples for HIV and HCV use a combination of target capture and amplification as taught and claimed by the Vysis '338 patent.

12. Based on my understanding of the development of Gen-Probe's assays and its TIGRIS instrument for detecting target polynucleotides, as described above, I believe Gen-Probe was not able to successfully develop an effective automated assay until it used the combination of target capture and amplification as taught and claimed by the '338 patent. I also believe it is likely that Gen-Probe was able to do so with the benefit of the experience and knowledge gained from the former Gene-Trak employees in its employ and thus copied Vysis's technology of combining target capture with amplification.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 10th day of November, 2000 at Downer's Grove, Illinois.

David J. Lane, Ph.D.